DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m3121n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

NOV 2 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Monica F. Abeles, President
Diasol, Inc.
13212 Raymer Street
North Hollywood, CA 91605

W/L 03-00

Dear Ms. Abeles:

During an inspection of your facility conducted on September 8 to 15, 1999 our investigator determined that your firm manufactures and distributes hemodialysis concentrate solutions. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to establish and implement procedures for monitoring and control of process parameters to ensure that each production run, lot, or batch of finished devices meets acceptance criteria [21 CFR 820.80(d)]. Specifically, your firm has not established any acceptance criteria for Limulus Amebocyte Lysate (LAL) or conductivity testing for your hemodialysis concentrate solutions. Additionally, our investigation determined that several lots of product were released for distribution prior to completion of the LAL testing.

- Failure to ensure that all production processes are validated with a high degree of assurance to ensure that all specified requirements are met [21 CFR 820.75(a)]. Specifically, your firm has no documented evidence to demonstrate that your hemodialysis concentrate solutions mixing operations meet their pre-determined specifications and quality attributes.

- Failure to ensure that all equipment used in the manufacturing process meets their specified requirements [21 CFR 820.70(g)]. Specifically, your firm has no documented evidence demonstrating that the cleaning processes used to sanitize your production drums and reverse osmosis (RO) water system will prevent contamination or will not have any adverse effects on the finished product.

- Failure to ensure that device history records demonstrate that the device is manufactured in accordance with the device master record [21 CFR 820.184]. Specifically, the device history records for your hemodialysis concentrate solutions do not specify the mixing times. Additionally, there is no written procedures used to reconcile the quantities of labeling issued, used and returned.

- Failure to ensure that device history records include the quantity of devices released for distribution [21 CFR 820.184(c)]. Specifically, three of five device history records reviewed lacked the quantity of products released to distribution.

- Failure to conduct quality audits to verify that the quality system is effective in fulfilling the quality system objectives [21 CFR 820.22]. Specifically, our inspection disclosed that your firm has no documented evidence that any quality audits have been conducted.

- Failure to ensure that acceptance procedures define inspections, test, or other verification activities of incoming products [21 CFR 820.80(a)]. Specifically, there are no procedures for verification of certificates of analysis to ensure that incoming sodium chloride. potassium chloride and magnesium meet there specified requirements. Our investigation disclosed that test results which exceeded their specified requirements were released into production.

- Failure to control complaint handling procedures to ensure that all oral and written complaints are documented upon receipt and properly evaluated [21 CFR 820.198(b)]. Specifically, our inspection disclosed that all necessary information for evaluation of complaints was not documented.

Our office disagrees with your argument that there is no need to validate your LAL testing methodology because it is a standard AAMI requirement. It is your responsibility to ensure that your LAL test will yield valid results with each product you test. This validation step for the LAL test is referred to as the Inhibition/Enhancement test in the LAL section of the USP.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified

by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Thomas L. Sawyer, Director, Compliance Branch and a copy to Dannie E. Rowland, Compliance Officer at U.S. Food and Drug Administration, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely,

James E Vazirk

Acting District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320